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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,105	09/07/1999	F. ABEL PONCE DE LEON	002076-013	4749

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	#20

DATE MAILED: 03/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/341,105	PONCE DE LEON ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 26 November 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/341,105 is acceptable and a CPA has been established. An action on the CPA follows.

Specification

2. The disclosure is objected to because of the following informalities:

The specification contains representations of nucleotide sequences that are not accompanied with the requisite SEQ ID NO.

Appropriate correction is required.

3. The use of the trademark TWEEN 20 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Objections

4. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Claim 1 is drawn to isolated DNA selected from a defined group. The invention of dependent claim 2, effectively expands the invention of Claim 1 by allowing for the presence of an infinite number of additional sequences.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *In re Wands*, 8 USPQ2d 1400 (CAFC 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Quantity of Experimentation Necessary

The amount of experimentation would be profound, requiring years of testing with little if any reasonable expectation of success.

The Amount of Direction or Guidance Provided

The specification provides at best limited guidance for confirming the source of the claimed sequences and provides but an invitation for others to experiment in determining the significance of the isolated sequences. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

The Presence or Absence of Working Examples

The specification shows that they have confirmed the source of the claimed nucleic acids (claims 1 and 2), and that at least some of these sequences hybridized to nucleic acid found in other avians, *i.e.* turkeys. Just what these sequences encode and what they indicate as a result of forming duplex structures with a target sequence is unknown.

It is noted with particularity that claim 5, and by default claims 1 and 3 from which claim 5 depends, is directed to the development of a genetic map for "avian species selected from the group consisting of chicken, turkey, partridge, duck, guinea hen, and goose." A review of the specification fails to find where a genetic map for such species has been developed or where reproducible conditions have been set forth that would enable one of skill in the art to develop such a genetic map.

The Nature of the Invention

The invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

> In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The State of the Prior Art

The area of art most to which the claimed invention is most closely related is quite undeveloped. While much effort has been spent in unraveling the nucleotide sequences of humans, and to determine which genes are encoded thereby and what conditions are associated with said sequences, little has been done with *Gallus* or other avians.

The Relative Skill of Those in the Art

The relative skill of those in the art most closely associated with the claimed invention is high, on par with those that hold a Ph.D. in biochemistry and that also have several years of laboratory experience.

While the specification does clearly identify several sequences, the specification must also enable their use. As set forth above, the specification has not been found to enable the use of the claimed sequences. While claims 3-7 are directed developing a genetic map, the specification has been found, at best, to provide only an invitation for others to experiment in the development of such. In support of this position, attention is directed to page 8 wherein is stated:

> It is expected based on our results that chicken chromosome painting probes can similarly be used in closely and distantly related avian species to identify gross chromosomal rearrangements such as translocations and duplications that have occurred during avian evolution. Since the chicken Z-chromosome sequences are highly conserved in turkey, the chicken Z-chromosome-specific microsatellite markers should be particularly useful for genetic mapping in turkey. (emphasis added)

The predictability or unpredictability of the art

The predictability of the art is low. The claimed nucleic acid sequences are genomic DNA that is from the chicken Z chromosome and which also binds to the Z chromosome of turkeys. While the DNA has been defined as being "marker DNA," the specification is silent as to just what,

other than the Z chromosome, it is marking. The sequences, as indicated above, are genomic and there is no indication that the sequences comprise any gene, and even if they did comprise an intact or partial gene sequence, just what the gene is or how it is to be used. The specification infers that the sequences could be used to develop "specific microsatellite linkage map" (Figure 2). Review of Figure 2, however, does not show how any one of the 19 sequences recited in Claim 1 correspond to any specific microsatellite marker, much less show that any one of the markers is useful.

Claims 6, 7, and 9 require one of skill in the art to not only use some or all of these 19 sequences so to construct multiple Z-chromosome specific microsatellite linkage maps, but to also employ same in the identification of chromosomal rearrangements, which is considered to encompass the prediction of any disease state and physiological condition of any avian. The ability of one to somehow take one or more of these 19 sequences from a chicken Z chromosome and identify any and all deletions, translocation, insertions of the Z chromosome in any avian is most unpredictable and to then apply same to predicting any physiological condition is most unpredictable. The , much less with the Z chromosome as found in turkeys, partridge, duck, guinea hen, and geese (claim 5).

The breadth of the claims

Claims 1 and 2 encompass not only the 19 sequences set forth in Claim 1, but also any number of additional sequences, from virtually any source, and in any concentration, as accorded by the limitation of claim 2 wherein the "isolated DNA" is part of a "library."

The method of claims 3-9 encompasses the generation of a microsatellite marker map for virtually any and every life form, and not just for every type of avian, and not just chicken, turkey, partridge, duck, guinea hen, and goose as set forth in claim 5. In support of this position, attention is directed to claim 3 where the method only requires that "at least one Z-chromosomal marker DNA according to Claim 1" is to be used "for genetic mapping." The specification does not set forth a repeatable procedure whereby a Z-chromosome-specific linkage map can be created for any life form, much less for each of the types of avian in claim 5, and lesser still for any and all other types of avians. While the specification has shown that there is a high degree of similarity between chicken and turkey Z chromosome, such similarity has not been shown to exist for widely divergent avian species, nor shown to exist for any other life form.

It is noted that narrowing limitations found in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. *In re Philips Industries v., State Stove & Mfg. Co.*, 522 F.2d 1137, 186 USPQ 458 (CA6 1975), 237 PTJA A-12. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into the claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 3-9 provide for the use of "at least one Z-chromosomal marker DNA," but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 3-9 are is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al.

12. For purposes of examination claims 1 and 2 have been interpreted as encompassing not only the 19 sequences set forth in claim 1 but also additional sequences as would be expected in the "library" of claim 2. Given that an independent claim is considered to encompass the

limitations of each of its dependent claims, the "isolated Z-chromosomal maker DNA" of claim 1 is considered to encompass such additional sequences.

13. Kim et al., disclose the use of a genomic library made from the DNA of chickens. Such a library would have as an inherent property at least one copy per cell of the Z chromosome (the Z chromosome is the sex chromosome for which cocks/capons have two copies and hens/pullets have but one copy). Accordingly, any genomic library derived from such a source would have as an inherent property the Z-chromosome-specific DNA sequences claimed presently.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bradley L. Sisson
Primary Examiner
Art Unit 1655

bls
January 30, 2002